‘Function First - Be Active, Stay Independent’ - Promoting physical function and physical activity in people with long-term conditions by primary care: A protocol for a realist synthesis with embedded co-production and co-design.

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Full title: 'Function First - Be Active, Stay Independent' - Promoting physical function and physical activity in people with long-term conditions by primary care: A protocol for a realist synthesis with embedded co-production and co-design.

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Abstract

Introduction:
People with long-term conditions typically have reduced physical functioning, are less physically active and therefore become less able to live independently and do the things they enjoy. Long-term conditions are managed routinely in primary care, however support rarely emphasises physical function and physical activity. This project aims to develop evidence-based recommendations about how primary care can optimally help people to become more physically active in order to maintain and improve their physical function, thus promoting independence.

Methods and analysis:
This study takes a realist synthesis approach, following RAMESES guidance, with embedded co-production and co-design. Stage 1 will develop initial programme theories about physical activity and physical function for people with long-term conditions, based on a review of the scientific and grey literature, and two multisector stakeholder workshops using LEGO® SERIOUS PLAY®. Stage 2 will involve focused literature searching, data extraction and synthesis to provide evidence to support or refute the initial programme theories. Searches for evidence will focus on physical activity interventions involving the assessment of physical function that are relevant to primary care. We will describe 'what works', 'for whom' and 'in what circumstances' and develop conjectured programme theories using (C)ontext, (M)echanism and (O)utcome (CMO) configurations. Stage 3 will test and refine these theories through individual stakeholder interviews. The resulting theory-driven recommendations will feed into Stage 4 which will involve three sequential co-design stakeholder workshops where practical ideas for service innovation in primary care will be developed.

Ethics and dissemination:

Healthcare and Medical Sciences Academic Ethics Committee (Reference 2018-16308) and NHS Wales Research Ethics Committee 5 approval (References 256729 and 262726) have been obtained. A knowledge mobilisation event will address issues relevant to wider implementation of the intervention and study findings. Findings will be disseminated through peer-reviewed journal publications, conference presentations, and formal and informal reports.

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Strengths and limitations of this study:

1. A realist approach facilitates explanation of the complexity of promoting physical activity and physical function as part of the management of long-term conditions in primary care, paying attention to the contextual factors that shape how interventions are implemented and generate impact.
2. The use of 'Collective Making' activities including LEGO® SERIOUS PLAY® for programme theory development and co-design will enable creative stakeholder engagement and expression through model-building, use of metaphor and story-telling.
3. Engagement and co-production with multi-sectoral stakeholders throughout the synthesis, and the addition of the co-design and knowledge mobilisation stages, will develop recommendations that are grounded in the real world and address practice and policy challenges.
4. Realist synthesis is about what works in what contexts, so the review recommendations will need further consideration and modification for application in different contexts.

Introduction

Three out of four older adults living in developed countries such as the UK have long-term conditions (58), and the prevalence rises with age, affecting 58% of people over 60 (1). Treatment and care for people with long-term conditions is estimated to account for £7 in every £10 of total UK health and social care expenditure, which will increase further as the population ages (57). This increasing prevalence is one of the biggest challenges facing our health and social care systems (82).

Major contributors to this challenge are the decline in physical function and physical activity characteristic to people with long-term conditions. 'Physical function' is an individual's capacity to undertake physical tasks and is one of the most important factors for quality of life (2, 3, 20). A different but related concept is 'physical activity', which can be defined as 'any bodily movement produced by skeletal muscles that results in energy expenditure' (79). Physical activity helps to prevent or delay functional decline and loss of independence (4, 5, 6, 8). Moreover, adults who become physically active later in life have similar mortality rates to those of lifelong exercisers (59). Helping people to be more physical active also has benefits for mental health and mood (60). Thus, improvements in physical activity and physical function has promising potential for substantially reducing costs to health and social care services (61, 62).

Caring for people with long-term conditions is a core component of primary care (9, 83), and is uniquely placed to empower individuals and communities (63). However, primary care management has typically focussed on the diagnosis and categorisation of disease, and the management of important mediators such as blood pressure and glycaemic control in diabetes (64), rather than any concomitant decline in physical function. Placing more emphasis on functional limitations may promote more pro-active, 'whole-person' and preventive care approaches, benefiting the patient and targeting healthcare resources more effectively (50, 51). Organisational interventions targeting patient-specific difficulties (e.g. functional ability), appear more likely to be effective (52), especially when the intervention is more comprehensive and better integrated into routine care (53).

Previous reviews have explored the effects of physical activity interventions in sedentary adults and those with long-term conditions in the primary care setting (e.g. 12, 13, 68, 69). Barriers and facilitators to physical activity and the effectiveness of different modes of delivery have been explored (14, 15, 65, 66, 70). NICE guidance has recommended brief physical activity advice as a way to prevent dementia, disability and frailty in later life (71, 72). However, whilst the links between physical activity and physical function are evident and the benefits of physical activity are clear, the best way for primary care to help people with long-term conditions increase physical activity and reduce functional decline is uncertain.

Optimising physical function and physical activity is likely to involve a complex intervention, given the range of potential influences (e.g. personal, social, condition and treatment related), and the range of resources that activate different responses in different people (16). A comprehensive understanding of an intervention, what it does and how it works, can facilitate meaningful application and improve sustainability (73). Therefore, it is important to understand the underlying theory and the critical components (or 'active ingredients') of an intervention, and a methodology which focuses on this complexity is required. A realist approach will provide a contextualized, explanatory account and understanding of 'what is it about a programme (or intervention) that works (or doesn't work) for whom, and in what circumstances' (17-19).

As well as the interrogation of relevant theory-rich literature, realist evidence syntheses are participatory in nature. They draw on the lived experiences of service users and professionals

providing services, to identify 'nascent' individual theories based on their experiences (38). To facilitate this, creative methods from the field of co-design will ensure that the views of all stakeholders are included and embedded within the process. The co-produced theory and ideas from these stakeholders will feed back into the literature searches, refining the search criteria, adding an interpretative frame to interrogate the literature, corroborating and refuting evidence. The resulting theories will then feed into a co-design stage where they will be further refined and prioritised before being applied to generate recommendations for service innovation and implementation.

Aims and objectives

1) To identify and produce a taxonomy of physical activity interventions that aim to reduce functional decline in people with long-term conditions managed in primary care.

2) To work with patients, health professionals and researchers to uncover the complexity associated with the range of physical activity interventions in primary care, and how they directly or indirectly affect the physical functioning of people with long-term conditions.

3) To identify the mechanisms through which interventions bring about functional improvements in people with long-term conditions, and the circumstances associated with how the interventions are organised and operate within different primary care contexts.

4) To understand the potential impacts of these interventions across primary care and other settings.

5) To co-produce an evidence-based, theory-driven explanatory account, in the form of refined programme theory.

6) To develop a new intervention through a co-design process with patients, health professionals and researchers.

Method and analysis

The established steps for a realist synthesis wil be followed, which include: clarifying the scope of the review, developing initial programme theory, evidence searching and appraisal, extracting data, synthesising evidence to test and refine the programme theory, drawing conclusions and recommendations (17).

Programme theory is defined here as 'the theory built into every programme (or intervention)' that addresses the facilitation of physical activity within primary care (36) and will be developed as 'context, mechanism and outcome propositions' (CMOs). The 'context' in this study refers to the 'settings within which programmes (or interventions) are placed, or pre-existing factors outside the control of programme designers (e.g. people's motivation, organisational contexts or structures)' (37). Mechanisms are sensitive to context and defined as 'how programmes (or interventions) change, or provide the resources for, people's decision-making (e.g. empowerment or confidence building) (36). 'Outcomes' may have single or multiple effects (38) and can be related to process (e.g. a change in behaviour) or impact (whether an intervention worked or not) (39).

This study involves 4 stages, detailed in the following sections and shown in Figure 1 below.

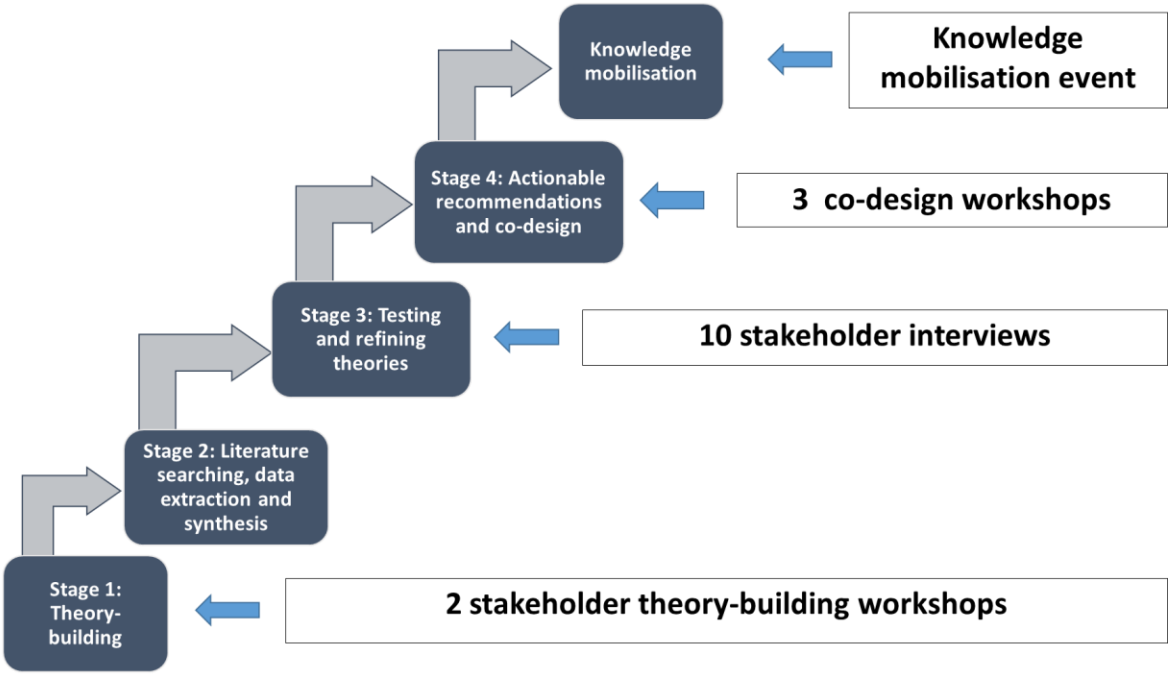

Figure 1. Schematic diagram of the 'Function First' realist evidence synthesis with co-design.

Stage 1 - Development of initial programme theory

The first stage of the synthesis will develop initial programme theories about how and why primary care interventions aiming to improve physical function and physical activity amongst patients with long-term conditions work (or may not work), for whom, and in which circumstances. These theories will be developed through two theory-building stakeholder workshops and a scoping review of published and grey literature.

A stakeholder analysis will identify and target the most relevant groups (40) with representation from patients, primary care professionals working in general medical practices, policy-makers, voluntary organisations, council-funded initiatives, social care, commissioners of services and NHS organisations from across the UK. Creative methods, borrowed from the field of co-design, will be employed to structure the workshops and elicit the views and experiences of all stakeholder representatives, including a facilitated session using LEGO® SERIOUS PLAY®. Following a series of skills-building activities, each individual will create and describe individual LEGO® models in response to the following questions: 'What does physical function mean to you?' and 'What are your experiences of maintaining physical function?' This will help to develop a shared understanding of the key topic areas and stimulate initial ideas and thoughts for theory development. These models will then be incorporated into a shared 'landscape' that begins to explore which aspects of these experiences helped or hindered the maintenance of physical function. Photographic images of the models will be captured and participant descriptions will be audio-recorded, and then transcribed for analysis, interpretation and shaping of emerging programme theories.

Theoretical landscape

The overarching theories and frameworks that are likely to inform the realist synthesis include: theories and models relating to physical function (e.g. International Classification of Function (20) environmental factors and individual compensation strategies) (21); psychological theories of motivation, behaviour and behaviour change relevant to patients and health professionals (e.g. self-

efficacy and self-determination theory (22, 23), intention and behaviour (31), health beliefs, planned behaviour(24, 25), interventions based around COM-B principles (Capability, Opportunity, Motivation - Behaviour) (26, 55); and the self-regulation of illness (54, 56); sociological theory (e.g. governmentality (27), habitus (28), social and peer support (29, 30), implementation theories (e.g. diffusion (32), knowledge to action (33), and organisational theories relevant to how interventions fit into different ways of delivering services and pathways (34, 35).
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Stage 2 – Literature searching, data extraction and synthesis

Literature searching

Unlike a traditional systematic review, a realist synthesis uses a more inclusive approach involving 'more heterogeneous evidence and an iterative process, which is less amenable to prescription but which needs to be equally rigorous' (42). Therefore, this stage will build on the scoping review of the literature, to involve further, more purposive searches enabling the initial programme theories developed in Stage 1 to be expanded.

We will review the existing literature to look for evidence to suggest how and for whom physical activity interventions work to optimise physical function in the primary care setting. It may be that interventions or services based in other areas of literature (such as secondary care, social services, the voluntary sector, or exercise science) also hold relevant insight for the development of the initial programme theories and therefore searches will not be restricted. The search strategy will be developed and amended for use with the following databases: Cochrane Library, MEDLINE, CINAHL, PsycInfo, Sociological Abstracts, Web of Science, Applied Social Sciences Index and Abstracts (ASSIA), Social Care Online and Social Care Institute for Excellence. We will also extend our searches to explore NHS reablement services (national and local) by searching the grey literature. Keywords will be developed from previous systematic reviews and the key themes, which underpin the initial programme theories, adapted for each information source as necessary.

We will identify references from previous relevant reviews, with forward citation tracking for key research studies. We will also draw on the expertise of the project team, external project advisory group, patient and public representatives, other key researchers (nationally and internationally) and organisations to ensure that we have not missed evidence that may be relevant but not visible through traditional systematic searching methods. We will also explore the literature using cluster search methods (41). Where necessary, we will seek further information and clarification by contacting authors of relevant reports and relevant organisations.

Our searches will include adults of all ages and socioeconomic backgrounds. We will translate non-English language papers where relevant and practical. We will not limit our searches by publication date and there will be no restriction on the type of publication or study type that can be included. We will examine published and unpublished literature including research articles, systematic reviews and documents detailing policy and local/national initiatives. Literature will be screened for relevance to the initial programme theories and cross-checked by two members of the research team.

We will *not s*earch for, nor include, studies that have limited transferability to NHS primary care, such as interventions involving pharmacological agents or very technical, high-cost equipment.

Data extraction

Consistent with the realist synthesis approach (17), the test for inclusion will be whether the evidence is 'good and relevant enough' to be included (43). Relevance is defined as the ability of the data to contribute to the programme theory (44). Assessment of relevance will involve seeking any

"trustworthy nuggets of information to contribute to the overall synthesis" (18). Rigour or whether the quality of the evidence is 'good enough' is the research team's judgement of the credibility of the data, including fidelity, trustworthiness and value (45). Bespoke data extraction forms will be designed to ensure that we capture data that informs the developing programme theories, including intervention details and any difference in implementation. If any discrepancies arise, we will discuss amongst the project team whether the evidence provided meets the criteria to be included.

Synthesis

This analytical stage will involve synthesising the evidence to elicit relationships between the contexts, mechanisms and outcomes. Through the research team's experience of conducting realist synthesis (46-48), suggestions from Pawson (18) and underpinned by the principles of realist enquiry, we will use the following approach:

1) Organisation of extracted information into evidence tables representing the different bodies of literature

2) Developing themes across evidence tables in relation to emerging patterns amongst the developing programme theories to seek confirming or refuting evidence

3) Linking patterns to develop hypotheses that support or refute the developing programme theories.

Following this process, a set of synthesised statements will be formed and a narrative summarising the nature of the links between context, mechanism and outcome will be developed (i.e. what works, for whom and in what circumstances). This will also summarise the characteristics of the evidence underpinning them. This process will involve ongoing, iterative discussion amongst the project team members and the project advisory group.

Stage 3 – Testing and refining programme theories

In order to refine the final programme theories, we will consult with stakeholders through up to 10 telephone interviews. Purposive sampling of the stakeholders will be informed by stakeholder analysis and will aim to provide a range of perspectives from patients, service delivery managers, policy makers, community-based professionals (e.g. the National Exercise Referral Scheme), commissioners and primary care professionals. This will also enable us to capture different implementation approaches and provider influences. A semi-structured interview topic guide will be used to elicit the views of stakeholders on their resonance with the developing programme theories. The approach used in the interviews will be a 'teacher–learner cycle' whereby the researcher presents the developing programme theories to the stakeholder ('teaching') and then verifies with the stakeholder where they need adjusting ('learning') to create an improved, refined version and a 'mutual understanding' of the developed programme theories (38). With permission, the telephone interviews will be audio-recorded and transcribed verbatim for descriptive analysis of the key themes arising during refinement of the programme theories.

The tested and refined programme theories arising from the evidence synthesis and stakeholder consultation will represent 'what works' to improve physical activity (e.g. changes related to empowerment), 'for whom' (e.g. people with long-term conditions or primary care professionals), and 'in what circumstances' (e.g. unpredictable changes in long-term condition or limited consultation time).

Stage 4 – Intervention co-design, actionable recommendations and knowledge mobilisation

The refined programme theories will form the basis of recommendations for an intervention which is specifically designed to bring about improved physical functioning and physical activity for people with long-term conditions managed in primary care. The recommendations for service innovation, and plans for making the intervention useable, will then be designed collaboratively with stakeholders.

A team of design researchers will facilitate three consecutive co-design workshops, involving purposively sampled stakeholders including: patients with long-term conditions, primary care clinicians such as GPs, nurses and therapists; practice mangers, health board managers and commissioners. The three co-design workshops will ideally involve the same (or similar) people in each so that ongoing ideas can be developed and expanded during each workshop. There will be key 'deliverables' from each workshop, and in between workshops, designers will work to develop ideas and provocations for the next workshop, termed 'design activities'.

Workshop 1 (Immersion):
In this workshop, participants will immerse themselves in the lived experience of people with long-term conditions and the professional experience of people involved in primary care service and delivery. Programme theories that have been developed in the earlier stages of the review will be presented to participants. All participants will make models or images that express and visualise their own personal knowledge and experience, and how these relate to the emerging programme theories, so that they can be shared and understood by the other participants. The context will be varied for these participants, and so this workshop will also provide an opportunity for sense-checking and further refinement of the programme theories. Giving everyone the same time and space to do this at the start of a co-design process, respects and values their history and personal narrative, enabling everyone to move forward onto the main purpose of the co-design process.

Deliverable: A collection of models and images that represent a shared understanding and appreciation of the evidence, experiences, practice and context relevant to primary care, physical function and physical activity for people with long-term conditions.

Design activity 1: Between Workshops 1 and 2 the designers will explore a breadth of existing interventions and analogous practices to be brought to Workshop 2 as provocations for new ideas. We will also invite participants to bring examples of existing interventions or resources relating to existing interventions, they have experience or knowledge of.

Workshop 2 (Hack):
This will begin with a series of creative activities designed to set the tone of the workshop and simultaneously give people confidence and familiarity in these types of activities. Participants will take part in activities designed to generate ideas and concepts using two-dimensional visualisations and sketches. These activities will use the collection of models and images developed in Workshop 1, together with any provocations supplied by the designers, to generate ideas and rough prototypes of what might work. Different combinations of models and prototypes will be explored, including how they might achieve some of the ideas, or get close to achieving some of the ideas, and consequently fulfil the recommendations included in the programme theories.

Deliverables:

(a) Generation of at least 10 concepts (e.g. managing changes in long-term conditions), prioritised by workshop participants. The prioritisation will be based on immediate expert opinion (from the workshop participants together with the research project team) using simple categories of 'novelty', 'technological feasibility' (performance and manufacturing), 'user desirability' (ease of use, acceptability for patients and healthcare professionals) and 'economic viability (49)'.

(b) Generation of images, models or rough prototypes which could be images, sketches or 3D models made out of paper, card, Lego or plasticine, or a digital model represented through a simple animation.

Design activity 2: Between Workshops 2 and 3 the designers will take the models or rough prototypes and make adjustments and refinements.

Workshop 3 (Co-design):
In this workshop the prototypes will be refined and selected. This will involve all participants testing and refining the ideas and models further and employing a shared prioritisation process to select the top three ideas. This will involve a 'Dragon's Den' style activity, where participants are split into teams. Each team would further develop a concept to present back to an invited panel of 'dragons' (user experts) who have not been involved in the study to date. This process provides useful critical feedback and will also be made into a 'celebratory event' to give participants a sense of closure.

Deliverable: Refinement and testing of the top three ideas for a functional intervention for primary care with one chosen following critical user feedback.

Design activity 3: The design team will make further adjustments based upon feedback and developments from the co-design workshop.

Knowledge mobilisation

As this review will explore what works, for whom and in what circumstances, it is likely that the developed intervention will have core components and an 'adaptable periphery' that can adjust to contextual factors. A knowledge mobilisation strategy will explore these implementation variations and help to ensure that the information generated and the developed intervention is desirable (useable, acceptable, accessible), feasible (technologically, and in operational terms) and viable (economic). To assist with this, we will hold a workshop specifically dedicated to 'knowledge mobilisation' which will explore how best to implement this prototype intervention or new way of working, in different ways, for different contexts, thus identifying any additional resources required to support the 'adaptation to context' features and inform intervention design.

Patient and public involvement

Two patient and public research partners were involved during the proposal stage of this project, and are part of the study management group, helping to develop and refine the research objectives and methods. Two further patient and public research partners are members of the independent project advisory group. A named individual within the project team (R-JL) provides ongoing support for their active involvement in the following research activities; writing of the protocol and ethics application, preparation of public-facing study materials, tasks involved in development and refinement of programme theories and recommendations, and dissemination. Patient and public involvement will be monitored and reported using established guidance (80, 81).

Discussion

This study will add new information to this research field by conducting a realist evidence synthesis of interventions designed to improve physical activity and physical functioning for people with long-term conditions managed in primary care. The development of realist programme theory and associated intervention recommendations through an iterative co-design creative process is a new

innovation. This proposal aligns with the priorities in current UK policies and recommendations (74, 75) and the findings will provide new understanding regarding how best to plan, implement and sustain physical activity interventions in primary care in order to reduce functional decline for people with long-term conditions. The synthesis findings and associated co-design outputs will lead to actionable recommendations for those involved in the organisation of health services, in particular primary care and their partners, for the benefit of patients.

Our approach to this realist evidence synthesis involves embedded co-production, using a systematic and interdisciplinary approach and involving 'sustained engagement with stakeholders, and their systems, in order to generate implementable knowledge with impact in healthcare and health' (78). The realist programme theories will be developed with input from stakeholders as 'co-producers' throughout the review process. For example, an adapted form of LEGO® SERIOUS PLAY® will be used as a way of eliciting and sharing relevant experiences and considering collectively what made these experiences 'successful' or 'unsuccessful' forms of sustaining physical activity or physical function.

Systematic and iterative searches of relevant literature, alongside stakeholder engagement throughout this synthesis, will allow us to offer explanatory theories about the role of primary care in promoting physical activity and physical function for people with long-term conditions (including consideration of the physical, psychological and social factors that influence motivation for activity, and the value attached to physical function). The co-design and knowledge mobilisation elements will use these theories to develop desirable, feasible and viable service innovations, generating additional insight, feedback and momentum for the next 'feasibility' phase of the research.

We anticipate that adopting the principles of co-design as part of this synthesis, and specifically the creative practises of fully engaging people in the process- at multiple time points, will nurture community-academic partnerships and facilitate eventual impact and implementation. These principles include: taking a systems perspective (i.e. recognising the interrelationships between parts of a system, rather than focusing on one part), positioning research as a creative activity with human experience at the core and considering power-sharing during the co-design process (76, 77).

Ethics and dissemination:

This study has been reviewed and approved by Bangor University Healthcare and Medical Sciences Academic Ethics Committee (Reference 2018-16308) and NHS Wales Research Ethics Committee 5 (References 256729 and 262726). Ethical considerations include, but are not limited to, informed consent, participant anonymity and confidentiality, the potential for distress, participant burden, reimbursement and honoraria and the right to withdraw from the study.

We will report our study findings using established guidance (44). A final report for the Health Service and Delivery Research series and publication of an open-access journal paper will be written. A key output of the knowledge mobilisation event will be content for a suite of dissemination materials, with the targeting of dissemination and methods used led by the stakeholders involved.

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Competing interests:

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: all authors had financial support from the National Institute for Health Research for the submitted work; JG is Chair of the Community Care Collaboration in Wrexham and NW is a GP partner at Plas Menai Surgery. No other relationships or activities that could appear to have influenced the submitted work.

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Author contributions:

The contributions of the authors to different aspects of this work were as follows: conceiving and designing the study and obtaining funding: R-JL, NW, LW, CB, BH, JL, JH, VM, AL, CL-S, PB; refining study design and obtaining ethical approval: R-JL, NW, LW, CB, BH, JL, JH, VM, AL, RP, CL-S, JG; writing and revising this manuscript (wholly or in part): R-JL, NW, LW, CB, BH, JL, JH, VM, AL, RP, CL-S, JG.

References

1) Department of Health. Long-term conditions compendium of Information. 2012. Report No.: 3rd edition.

2) Fried TR, McGraw S, Agostini JV, Tinetti ME. Views of older persons with multiple morbidities on competing outcomes and clinical decision-making. J Am Geriatr Soc. 2008 Oct;56(10):1839-44.

3) Zubritsky C, Abbott KM, Hirschman KB, Bowles KH, Foust JB, Naylor MD. Health-related quality of life: expanding a conceptual framework to include older adults who receive long-term services and supports. Gerontologist. 2013 Apr;53(2):205-10.

4) Rantanen T, Guralnik JM, Sakari-Rantala R, Leveille S, Simonsick EM, Ling S, et al. Disability, physical activity, and muscle strength in older women: the Women's Health and Aging Study. Arch Phys Med Rehabil. 1999 Feb;80(2):130-5.

5) Keysor JJ. Does late-life physical activity or exercise prevent or minimize disablement? A critical review of the scientific evidence. Am J Prev Med. 2003 Oct;25(3 Suppl 2):129-36.

6) Howe TE, Rochester L, Neil F, Skelton DA, Ballinger C. Exercise for improving balance in older people. Cochrane Database Syst Rev. 2011 Nov 9;(11):CD004963. doi(11):CD004963.

~~7) Kendrick D, Kumar A, Carpenter H, Zijlstra GA, Skelton DA, Cook JR, et al. Exercise for reducing fear of falling in older people living in the community. Cochrane Database Syst Rev. 2014 Nov 28;(11):CD009848. doi(11):CD009848.~~

8) Kumar A, Delbaere K, Zijlstra GA, Carpenter H, Iliffe S, Masud T, et al. Exercise for reducing fear of falling in older people living in the community: Cochrane systematic review and meta-analysis. Age Ageing. 2016 May;45(3):345-52.

9) Royal College of General Practitioners. Health Select Committee Inquiry on Management of Long-Term Conditions. 2013. https://www.rcgp.org.uk/policy/rcgp-policy-areas/long-term-conditions.aspx

10) Williamson W, Kluzek S, Roberts N, Richards J, Arden N, Leeson P, et al. Behavioural physical activity interventions in participants with lower-limb osteoarthritis: a systematic review with meta-analysis. BMJ Open. 2015 Aug 10;5(8):e007642,2015-007642.

11) Howlett N, Trivedi D, Troop NA, Chater AM. What are the most effective behaviour change techniques to promote physical activity and/or reduce sedentary behaviour in inactive adults? A systematic review protocol. BMJ Open. 2015 Aug 5;5(8):e008573,2015-008573.

12) Sanchez A, Bully P, Martinez C, Grandes G. Effectiveness of physical activity promotion interventions in primary care: A review of reviews. Prev Med. 2015 Jul;76 Suppl:S56-67.

13) Geneen LJ, Moore RA, Clarke C, Martin D, Colvin LA, Smith BH. Physical activity and exercise for chronic pain in adults: an overview of Cochrane Reviews. Cochrane Database Syst Rev. 2017 Jan 14;1:CD011279.

14) Drennan VM, Halter M, Brearley S, Carneiro W, Gabe J, Gage H, et al. Investigating the contribution of physician assistants to primary care in England: a mixed-methods study. Health Services and Delivery Research. 2014 May;2(16).

15) Tulloch H, Fortier M, Hogg W. Physical activity counseling in primary care: who has and who should be counseling? Patient Educ Couns. 2006 Dec;64(1-3):6-20.

16) Hewitt G, Sims S, Harris R. The realist approach to evaluation research: an introduction. International Journal of Therapy and Rehabilitation. 2012 05/01; 2017/09;19(5):250-9.

17) Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review – a new method of systematic review designed for complex policy interventions. Journal of health services research & policy. 2005;10(Suppl. 1):21-34.

18) Pawson R. Evidence-based policy. A realist perspective. London: Sage Publishing; 2006.

19) Pawson R. The science of evaluation. A realist manifesto. London: Sage; 2013.

20) World Health Organisation. International classification of functioning, disability and health. . 2001.

21) Tomey KM, Sowers MR. Assessment of physical functioning: a conceptual model encompassing environmental factors and individual compensation strategies. Phys Ther. 2009 Jul;89(7):705-14.

22) Bandura A. Self-Efficacy: The Exercise of Control. New York: W.H. Freeman; 1997.

23) Deci EL, Ryan RM. Intrinsic Motivation and Self-Determination in Human Behavior. New York: Plenum Press; 1985.

24) Ajzen I, Fishbein M. The prediction of behavior from attitudinal and normative beliefs. Journal of Personality and Social Psychology. 1970;6:466-87.

25) Ajzen I. The theory of planned behaviour. Organizational Behavior and Human Decision Processes. 1991;50:179-211.

26) Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implement Sci. 2011 Apr 23;6:42,5908-6-42.

27) Foucalt M. On Governmentality. In: Ideology and Consciousness. ; 1979. p. 5-21.

28) Bourdieu P. Outline of a Theory of Practice. Cambridge: Cambridge University Press; 1977.

29) Orsega-Smith EM, Payne LL, Mowen AJ, Ho C, Godbey GC. The Role of Social Support and Self-Efficacy in Shaping the Leisure Time Physical Activity of Older Adults. Journal of Leisure Research. 2007;39(4):705-27.

30) Lindsay Smith G, Banting L, Eime R, O'Sullivan G, van Uffelen JGZ. The association between social support and physical activity in older adults: a systematic review. Int J Behav Nutr Phys Act. 2017 Apr 27;14(1):56,017-0509-8.

31) Eccles MP, Hrisos S, Francis J, Kaner EF, Dickinson HO, Beyer F, et al. Do self- reported intentions predict clinicians' behaviour: a systematic review. Implement Sci. 2006 Nov 21;1:28.

32) Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Q. 2004;82(4):581-629.

33) Wilson KM, Brady TJ, Lesesne C, NCCDPHP Work Group on Translation. An organizing framework for translation in public health: the Knowledge to Action Framework. Prev Chronic Dis. 2011 Mar;8(2):A46.

34) Easterby-Smith M. Disciplines of Organizational Learning: Contributions and Critiques. Human Relations. 1997 09/01; 2017/09;50(9):1085-113.

35) Dewing J. Chapter 15 Becoming and Being Active Learners and Creating Active Learning Workplaces. In: McCormack B, Manley K, Wilson MV, editors. The Value of Active Learning in International Practice Development in Nursing and Healthcare. Oxford Blackwells; 2008. p. 273-94.

36) Westhorp G, Prins E, Kusters C, Hultink M, Guijt I, Brouwers J. Realist Evaluation: An Overview. Wageningen: Centre for Development Innovation; 2011.

37) Timmins P, Miller C. Making evaluations realistic: the challenge of complexity. Support for Learning. 2007;22(1):9-16.

38) Pawson R. Realistic Evaluation. London: Sage Publications; 1997.

39) Kazi MAF. Realist evaluation in practice. Health and Social Work. London: Sage Publications; 2003.

40) Spitters HP, Lau CJ, Sandu P, Quanjel M, Dulf D, Glumer C, et al. Unravelling networks in local public health policymaking in three European countries - a systems analysis. Health Res Policy Syst. 2017 Feb 3;15(1):5,016-0168-2.

41) Booth A, Harris J, Croot E, Springett J, Campbell F, Wilkins E. Towards a methodology for cluster searching to provide conceptual and contextual "richness" for systematic reviews of complex interventions: case study (CLUSTER). BMC Med Res Methodol. 2013 Sep 28;13:118,2288-13-118.

42) McCormack B, Dewar B, Wright J, Garbett R, Harvey G, Ballantine K. A Realist Synthesis of Evidence Relating to Practice Development. NHS Quality Improvement Scotland; 2006.

43) Rycroft-Malone J, McCormack B, Hutchinson AM, DeCorby K, Bucknall TK, Kent B, et al. Realist synthesis: illustrating the method for implementation research. Implement Sci. 2012 Apr 19;7:33,5908-7-33.

44) Wong G, Greenhalgh T, Westhorp G, Buckingham J, Pawson R. RAMESES publication standards: realist syntheses. BMC Med. 2013 Jan 29;11:21,7015-11-21.

45) Rycroft-Malone J, Burton CR, Williams L, Edwards S, Fisher D, Hall B, et al. Improving skills and care standards in the support workforce for older people: a realist synthesis of workforce development interventions. Health Services and Delivery Research. 2016;4(12).

46) Williams NH, Roberts JL, Din NU, Totton N, Charles JM, Hawkes CA, et al. Fracture in the Elderly Multidisciplinary Rehabilitation (FEMuR): a phase II randomised feasibility study of a multidisciplinary rehabilitation package following hip fracture. BMJ Open. 2016 Oct 5;6(10):e012422,2016-012422.

47) Burton C, Rycroft-Malone J, Williams L, Davies S, McBride A, Hall B, et al. Managers' use of nursing workforce planning and deployment technologies: protocol for a realist synthesis of implementation and impact. BMJ Open. 2016 Aug 26;6(8):e013645,2016-013645.

48) Williams L, Rycroft-Malone J, Burton CR, Edwards S, Fisher D, Hall B, et al. Improving skills and care standards in the support workforce for older people: a realist synthesis of workforce development interventions. BMJ Open. 2016 Aug 26;6(8):e011964,2016-011964.

49) Brown T. Design Thinking. Harvard Business Review. 2008.

50) Bierman AS. Functional status, the sixth vital sign. Journal of General Internal Medicine. 2001;16:785-786.

51) Richardson J, Letts L, Chan D, Officer A, Wojkowski S, Oliver D, et al. Monitoring physical functioning as the sixth vital sign: evaluating patient and practice engagement in chronic illness care in a primary care setting--a quasi-experimental design. BMC Fam Pract. 2012 Apr 3;13:29,2296-13-29.

52) Smith SM, Soubhi H, Fortin M, Hudon C, O'Dowd T. Interventions for improving outcomes in patients with multimorbidity in primary care and community settings. Cochrane Database Syst Rev. 2012 Apr 18;4:CD006560.

53) Coulter A, Entwistle VA, Eccles A, Ryan S, Shepperd S, Perera R. Personalised care planning for adults with chronic or long-term health conditions. Cochrane Database Syst Rev. 2015 Mar 3;(3):CD010523. doi(3):CD010523.

54) Leventhal, H., Nerenz, D.R. and Steele, D.J. (1984). Illness representations and coping with health threats. In A. Baum, S.E. Taylor and J.E. Singer (eds), *Handbook of Psychology and Health: Social Psychological Aspects of Health*, Vol. 4. Hillsdale, NJ: Lawrence Erlbaum.

55) Michie, S., Ashford, S., Sniehotta, F.F. et al. (2011). A refined taxonomy of behaviour change techniques to help people change their physical activity and health eating behaviours: the CALO-RE. Psychology and Health, 26: 1479–98.

56) Cameron, L.D. and Leventhal, H. (eds) (2003). The Self-regulation of Health and Illness Behaviour. London: Routledge.

57) Projections of multi-morbidity in the older population in England to 2035: estimates from the Population Ageing and Care Simulation (PACSim) model. Andrew Kingston, Louise Robinson, Heather Booth, Martin Knapp, Carol Jagger, for the MODEM project. Age and Ageing, Volume 47, Issue 3, May 2018, Pages 374–380, https://doi.org/10.1093/ageing/afx201

58) Marengoni A, Angleman S, Melis R, et al. Aging with multimorbidity: a systematic review of the literature. Ageing Res Rev 2011;10:430–9.doi:10.1016/j.arr.2011.03.003

59) Saint-Maurice PF, Coughlan D, Kelly SP, et al. Association of Leisure-Time Physical Activity Across the Adult Life Course With All-Cause and Cause-Specific Mortality. JAMA Netw Open. Published online March 08, 20192(3):e190355. doi:10.1001/jamanetworkopen.2019.0355

60) Older people: independence and mental wellbeing NICE guidance 2015

61) The economic burden of physical inactivity: a global analysis of major non-communicable diseases. Ding, et al.:July 27, 2016DOI:https://doi.org/10.1016/S0140-6736(16)30383-X

62) McNally Scarlett, Nunan David, Dixon Anna, Maruthappu Mahiben, Butler Kenny, Gray Muir et al. Focus on physical activity can help avoid unnecessary social care BMJ 2017; 359 :j4609

63) A vision for primary health care in the 21st century: towards universal health coverage and the Sustainable Development Goals. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2018 (WHO/HIS/SDS/2018.X). Licence: CC BY-NC-SA 3.0 IGO. https://www.who.int/health-topics/primary-health-care#tab=tab_1

64) The role of the Quality and Outcomes Framework in the care of long-term conditions: systematic review. Lindsay JL Forbes, Catherine Marchand, Tim Doran, Stephen Peckham. British Journal of General Practice 2017; 67 (664): e775-e784. DOI: 10.3399/bjgp17X693077

65) Referral for Expert Physical Activity Counseling: A Pragmatic RCT. James, Erica L. et al. American Journal of Preventive Medicine, Volume 53, Issue 4, 490 – 499

66) Integrating Physical Activity in Primary Care Practice -AuYoung, Mona et al. The American Journal of Medicine, Volume 129, Issue 10, 1022 – 1029
67) https://rdcu.be/bUVe3
68) Waugh https://www.ncbi.nlm.nih.gov/pubmed/29920972
69) Larun L, Brurberg KG, Odgaard-Jensen J, Price JR. Exercise therapy for chronic fatigue syndrome. Cochrane Database of Systematic Reviews 2019, Issue 10. Art. No.: CD003200. DOI: 10.1002/14651858.CD003200.pub8.
70) Physical activity counseling in primary care and family medicine residency training: a systematic review. Apichai Wattanapisit, Titiporn Tuangratananon & Sanhapan Thanamee
BMC Medical Education volume 18, Article number: 159 (2018)
71) NICE – NG 16 – Preventing dementia, disability and frailty
72) NICE Brief PA advice
73) Davidoff F, Dixon-Woods M, Leviton L, et al. Demystifying theory and its use in improvement BMJ Quality & Safety 2015;24:228-238. https://qualitysafety.bmj.com/content/24/3/228
74) Chief Medical Officer's report 2019 https://www.gov.uk/government/publications/physical-activity-guidelines-uk-chief-medical-officers-report
75) NHS long-term plan - https://www.longtermplan.nhs.uk/
76) Langley collective making paper - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6060522/
77) Greenhalgh paper - Greenhalgh T, Jackson C, Shaw S, Janamina T. Achieving research impact through co-creation in community-based health services: literature review and case study. Millbank Q. 2016;94:392–429. https://onlinelibrary.wiley.com/doi/full/10.1111/1468-0009.12197
78) Rycroft-Malone J, Burton CR, Bucknall T, Graham ID, Hutchinson AM, Stacey D. Collaboration and Co-Production of Knowledge in Healthcare: Opportunities and Challenges. Int J Health Policy Manag. 2016 Jan 28;5(4):221-3.
79) Caspersen CJ, Powell KE, Christenson GM. Physical activity, exercise, and physical fitness: definitions and distinctions for health-related research. Public Health Rep. 1985 Mar-Apr;100(2):12631.
80) Staniszewska S, Brett J, Simera I, Seers K, Mockford C, Goodlad S et al. GRIPP2 reporting checklists: tools to improve reporting of patient and public involvement in research BMJ 2017; 358 :j3453
81) https://www.invo.org.uk/posttypepublication/national-standards-for-public-involvement/
National Standards for Public Involvement, 2019
82) https://www.health.org.uk/publications/understanding-the-health-care-needs-of-people-with-multiple-health-conditions
83) https://www.kingsfund.org.uk/projects/time-think-differently/trends-disease-and-disability-long-term-conditions-multi-morbidity